

**LABEL IN PART:** (Bags) "Elmore Complete Market Egg Ration (1A) \* \* \* Arsanilic Acid—0.01% \* \* \* Manufactured by Elmore Milling Company, Inc." and "Elmore Complete Market Egg Ration (1A) \* \* \* 3-Nitro-4 Hydroxyphenylarsonic Acid—0.005% \* \* \* Manufactured by Elmore Milling Company, Inc., Oneonta, New York."

**LIBELED:** 5-14-60, Dist. Vt.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from and its quality fell below that which it purported and was represented to possess since the 22-bag lot contained less than the declared amount of arsanilic acid, and the 6-bag lot contained less than the declared amount of 3-nitro-4 hydroxyphenylarsonic acid.

The libel alleged also that another article known as "Hog Ration" was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

**DISPOSITION:** 6-3-60. Consent—destruction.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

**6213. Tranquilease (cosmetic cream).** (F.D.C. No. 41505. S. No. 4-382 P.)

**QUANTITY:** 48 individually cartoned jars at Washington, D.C.

**SHIPPED:** 1-20-58, from Philadelphia, Pa., by Denney & Denney, Inc.

**LABEL IN PART:** (Jar) "TRANQUILEASE - FRANCES DENNEY The Original Cosmetic Tranquilizer for the Skin \* \* \* 1.8 Oz. Net."

**ACCOMPANYING LABELING:** Carton inserts entitled "Tranquilease The only cosmetic of its kind" and leaflets entitled "Bulletin from Frances Denney."

**RESULTS OF INVESTIGATION:** Analysis showed that the article was a white, perfumed oil-in-water cream emulsion containing glycerol monostearate, waxes (including lanolin and/or sterols), inorganic pigments (mostly zinc oxide and titanium dioxide), mineral oil, glycerol, and a nitrogen compound (probably an amide).

**LIBELED:** 4-4-58, Dist. Columbia.

**CHARGE:** 502(a)—when shipped, the labeling and the name of the article contained false and misleading representations that the article would tranquilize the skin and correct all abnormal skin conditions resulting from emotional upsets, tension, and fatigue.

The libel alleged also that the article was misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics.

**DISPOSITION:** On 5-15-58, Frances Denney and Denney & Denney, Inc., appeared as claimants and denied that the article was a drug or that it was misbranded. Thereafter, the Government and the claimants filed written interrogatories. The claimants objected in part to the Government's interrogatories for specific reasons, and a further general objection was made to all the interrogatories on the grounds of self-incrimination. On 11-14-58, the court entered the following memorandum opinion, ruling against the claimants on their self-incrimination objection, and ruling in part for the claimants and in part for the Government on the other objections (23 F.R.D. 192):

\*See also Nos. 6203, 6205, 6207-6211.

TAMM, *District Judge*: "This suit is one in libel filed by the United States of America under Title 21, United States Code, Secs. 301, et seq. and prays for seizure and condemnation of a certain article of drug and cosmetic on the ground that the article was misbranded when introduced into, and while in interstate commerce, within the meaning of the Federal Food, Drug and Cosmetic Act.

"Subsequent to proper process and publication, the libellee filed its answer to the libel of information and denies that the article is a drug, denies that there was labeling, and denies that there was misbranding. It asserts that the name, 'Tranquilease,' is a coined word and has no meaning aside from the meaning given it by naming this product.

"The claimants, Frances Denney and Denney and Denney, Pennsylvania corporations, addressed interrogatories under Rule 33, Federal Rules of Civil Procedure, to the libellant and said interrogatories were answered. Libellant, United States of America, then addressed interrogatories to the claimants—said interrogatories being objected to by the claimants mainly on the ground that 'disclosure of the information requested might tend to incriminate any responsible corporate officer or agent called on to furnish information on behalf of claimants in violation of the Fifth Amendment.' Other objections are based upon irrelevancy, revelation of a trade secret without a showing of its need by the libellant and an attempt to secure the results of work performed by experts.

"Subsequently, on August 20, 1958, the claimant corporations and their president William F. Denney were named in and served with a notice of hearing preliminary to a determination whether criminal action will be undertaken. This is the factual background upon which the claimants base their objections to the interrogatories served by the libellant, United States of America. The claimants allege that if they are required to answer the interrogatories the answer will, or may possibly, serve as the basis for a criminal action, and thus they would be testifying against themselves in violation of the Fifth Amendment. The threat of a criminal action is more than a bare possibility as seen from the 'Notice of Hearing,' 'Charge Sheet,' and other papers served upon the corporations and their president.

#### Objection based on self-incrimination.

"All parties to this action do agree that corporations do not have the right, as do individuals, to assert the privilege against self-incrimination. The argument of the United States stems directly from this basic concept for it asserts that since corporations are the parties to this action and not individuals, the privilege against self-incrimination does not play a part in this proceeding. However, the libellees answer this contention by saying that because of the broad criminal liability imposed by the Federal Food, Drug and Cosmetic Act, whoever answers these interrogatories puts himself, personally, in a responsible relation to the corporation, and under the reasoning of the case of *United States v. Dotterweich*, 320 U.S. 277, tends to incriminate himself.

"In the *Dotterweich* case, *supra*, the Court through Mr. Justice Frankfurter discussed the history of the present code provision and its development from the Food and Drugs Act of 1906. The Court also pointed out that 'such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good, it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.' (P. 281)

The Court continues:

The Act is concerned not with the proprietary relation to a misbranded or an adulterated drug, but with its distribution. In the case of a corporation such distribution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor.  
(P. 283)

\* \* \*

The Circuit Court of Appeals was evidently tempted to make such a de-vitalizing use of the guaranty provision through fear that an enforcement

of § 301(a) as written might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment. But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. (p. 284)

“Thus, it is seen that regardless of conscious fraud, anyone who shares in the responsibility in the business process resulting in unlawful distribution commits an offense. This is the basis for the reasoning of the libellees. They argue that ‘after a notice of hearing has been served, any one of claimant’s officers or agents who undertakes to answer these interrogatories on behalf of the corporation fixes his position as one who stands in “responsible” relation to the corporation and thereby tends to incriminate himself under *Dotterweich*.’

“However, this Court does not believe that the holding of the *Dotterweich* case, *supra*, is to be applied as broadly as libellees contend. It is apparent from the *Dotterweich* case that one will be held criminally liable if he has a responsible share in the furtherance of the acts which the statute outlaws. However, to adopt the position contended for by the libellees is equivalent to saying that one who answers interrogatories addressed to the corporation automatically assumes a responsible relation or share in the furtherance of the outlawed transaction merely by answering interrogatories. But answering interrogatories is not what the statute outlaws. It is true that the corporation, in selecting an officer or agent to answer the interrogatories, could conceivably select one who, without being conscious of doing so, would be answering questions that would tend to incriminate himself. However, it is more rational to assume that since the corporations and their president have been advised in what manner they have allegedly violated the statute and have knowledge of all who were in a responsible relation to such violation, they also have knowledge of those who were not involved. Therefore, the libellees could select to answer the interrogatories to the best of his ability one who would not thereby be incriminated. Merely because a person is an officer or agent of the corporations does not per se mean that he automatically stands in a position of criminal liability, for the *Dotterweich* case specifically holds that a person must have a responsible share in the furtherance of the transactions which the statute outlaws.

“In the case of *Paul Harrigan & Sons, Inc. v. Enterprise Animal Oil Co., Inc.*, U.S.D.C., E.D. Pa. (1953, 18 Fed. Rules Serv. 33.325, Case 1), a similar situation arose. In that case, a private civil action, all of the defendants were also defendants in pending criminal proceedings. All of the officers of the corporate defendants who had knowledge of the facts and were authorized to answer interrogatories had been indicted individually. The plaintiff propounded interrogatories to each of the defendants sued in the civil action—the interrogatories seeking information and records concerning acts of the defendants which could serve as part of the proof of the criminal charges which were pending. Objections were made to the interrogatories on the ground that if the defendants were compelled to answer, they would be testifying against themselves in violation of the Fifth Amendment. As to the corporate defendants, the Court wrote:

\* \* \* a twofold problem is presented. First the information sought is within the knowledge of officers who have been indicted individually and secondly, all those officers who are authorized to answer interrogatories have also been indicted individually.

“The Court, in holding that the objections to the interrogatories were well founded and would be sustained, went further and wrote:

\* \* \* it appears to the court that the interests of justice require the application of the principle enunciated in Rule 30(b) and discovery, insofar as it relates to the indicted defendants, will be postponed until the termination of the criminal action. While this will, undoubtedly, cause inconvenience and delay to the plaintiff, protection of the defendants' constitutional rights is the more important consideration.

"In a more recent case, *United States v. 42 Jars 'Bee Royal Capsules'*, 25 Fed. Rules Serv., 33,325, Case 1, U.S.D.C. New Jersey (1958), a different solution was reached to a problem similar in nature to the one before this Court.

"Bee Royale, Inc., a New York corporation, was the claimant of the seized goods. During the discovery proceedings, the claimant objected to interrogatories asked of it by the libellant. The objections were based on a denial of the constitutional privilege of freedom from self-incrimination. The court decided the case on the basic ground that since the privilege against self-incrimination is given only to natural persons, the corporation may not refuse to answer the interrogatories on this ground. The solution ordered by that court was as follows: (p. 557)

True it is that the answer of this corporation to this interrogatory must be sworn to by some individual who is its 'officer or agent,' who shall furnish such information as is available to the party. F.R.C.P. 33. Of course, if any such officer or agent, who is directed by the corporation to make these answers, can establish that such answers will incriminate him, he can refuse to answer them because of his right to avail himself of the aforesaid privilege. *U.S. v. White, supra*. But if the corporation select such a person to answer these interrogatories, and, because of his pleading this privilege, these interrogatories are therefore not answered, the corporation itself will be in default, for not making the requisite discovery under the rules. It will thus be the clear *duty of the corporation to select an officer or agent for the above purpose, who will not have personally participated in anywise in any such questionable transaction, and who thus cannot be incriminated by such answers*. This the corporation can easily do under its broad corporate powers, using even its attorney, for instance, whose duty it would then be to 'furnish such information as is available to the party'—the sum total of the corporate information. \* \* \* (Emphasis supplied)

It therefore follows that since (1) this corporation can appoint some officer or agent to answer interrogatories for it who will not be personally incriminated by such answers, and since (2) the corporation itself cannot claim any privilege against self-incrimination, it has no right to plead that privilege, as an objection to answering the interrogatories here in question.

"No mention of the *Dotterweich* case, *supra*, is made in the foregoing opinion, as the libellees have pointed out in their points and authorities.

"Thus, from the foregoing cases, it seems that two courses are open to this Court:

1. Require the corporation to select an officer or agent to answer the interrogatories—that is—an agent who will not incriminate himself by any answers, or
2. Stay discovery proceedings in the libel suit until the criminal proceedings have been completed.

"This Court is of the opinion that the proper course to follow in this case is to require the corporations to appoint an officer or agent who will not be incriminated by his actions to answer the interrogatories, and the Court, accordingly, directs that this be done.

#### Interrogatory No. 6.

"Interrogatory No. 6 is as follows:

What meaning do claimants intend to convey to the public by the following expressions used in the labeling:

- (a) Tranquilizer for the skin
- (b) Give a tranquil effect to the skin
- (c) Lull the skin

- (d) Pacify the complexion
- (e) Calm the skin
- (f) A corrective preparation
- (g) Relieve the modern problem of the skin.

"Claimants object to this interrogatory on the ground that it is irrelevant and that intended use is to be determined from the representations in the labeling. The libellant contends that this is relevant for it applies to the issue as to whether 'Tranquilease' is a drug. While the contention of the libellant is true, it is equally true—as libellees contend—that this determination should be made from the labeling itself. In all the authorities cited to this Court, this determination was made from an analysis of the labeling itself, as for example in the case of *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, etc.*, 113 F. Supp. 336 (1953). Therefore, this Court concludes that the objection to Interrogatory No. 6 is well founded, and the objection will be sustained.

Interrogatory No. 8.

"Interrogatory No. 8 is as follows:

- (a) What is the quantitative and qualitative formula for 'Tranquilease'?
- (b) Which ingredients in 'Tranquilease' are the active ingredients?
- (c) Explain the action of each active ingredient.

"Claimants object to this interrogatory on the ground that to require a disclosure would, in effect, be disclosure of a trade secret. *Moore's Federal Practice*, Sec. 26.22(3) states:

While there is no definite privilege against discovery of trade secrets and secret processes the courts will normally hesitate to require disclosure of such matters, and Rule 30(b) provides that the court may order 'that secret processes, developments, or research need not be disclosed.' But if the information is relevant and necessary to the presentation of the case, it will be required. The court may impose special conditions to protect the party.

"A determination of a question such as this usually lies within the discretion of the Court. In the case of *V. D. Anderson Co. v. Helena Cotton Oil Co.*, 117 F. Supp. 932, 941, there is the following:

With reference to the plaintiff's objections that some of the defendant interrogatories will require the disclosure of 'confidential information,' it may be said, generally speaking, that trade secrets are not privileged; while the Court has the power, under the provisions of Rule 30(b) to direct that such secrets need not be disclosed, nevertheless, 'if the information is relevant and necessary to the presentation of the case, it will be required,' and the court 'may impose special conditions to protect the party.'

"The Court in that case rejected that objection to the interrogatory.

"This Court concludes that the obvious relevancy and materiality of the interrogatory plus its necessity must outweigh the objection advanced by the libellees, and therefore, the objection to Interrogatory No. 8 is overruled.

Interrogatories Nos. 11 and 12.

"Interrogatories No. 11 and No. 12 are as follows:

- 11. State whether claimants have conducted any clinical tests to support the statements made in answer to questions 9 and 10 above.
  - (a) If so, state the name of the person conducting the tests, and the time and place at which conducted.
  - (b) Give the results of such tests.
- 12. Give the names of any physicians or dermatologists contacted by the claimants who support claimants' contentions concerning the effect of Tranquilease upon the skin.
  - (a) State the date such physicians or dermatologists were first contacted by claimants.

"Claimants object to these interrogatories mainly on the ground that they 'represent an attempt to secure the results of work performed by experts who are generally, and particularly in Food and Drug cases, shielded from interrogation by the opposing party.' The libellant argues that the interrogatories are directed towards obtaining information concerning the work of experts who should have been employed by the claimants even before the case arose and that they are relevant. The general rule in situations such as this is perhaps best expressed by Moore in *Moore's Federal Practice*, Sec. 26.24, p. 1158, who writes:

The court should not ordinarily permit one party to examine an expert engaged by the adverse party, or to inspect reports prepared by such experts, in the absence of a showing that the facts or the information sought are necessary for the moving party's preparation for trial and cannot be obtained by the moving party's independent investigation or research.

"Although the Government has not made an express or affirmative showing that this information is necessary for preparation for trial and cannot be obtained by its independent investigation or research, yet a main issue in the case is whether the claims made of 'Tranquilease' are false and misleading. The questions propounded by the libellant are directed to tests, if any, and experts, if any, that will support the position of the claimants on the issue of whether the claims made for the article are false or misleading. It appears from the questions themselves that they are requesting matter of such a nature that it is within the possession or knowledge of the claimants only and that the libellant can in no way obtain such information through independent investigation or research. In the case of *U.S. v. 132 Cartons \* \* \* Chloresium Tooth Paste*, decided March 27, 1950, U.S.D.C. for Dist. of Connecticut, Judge Hincks wrote the following:

\* \* \* I have come to the conclusion that to facilitate its cross-examination of claimant's witnesses and to prepare its rebuttal to claimant's defense the government is entitled to the discovery through the proposed deponents which it names of all matters not privileged. \* \* \* Libellant insisted that the discovery was necessary not to elicit their opinions as experts but rather to ascertain the factual scope and nature of the research done so that it possibly may be in a better position to cross-examine these witnesses on trial and prepare a rebuttal to the claimant's defense. Having in mind that the field in question here is one of scientific controversy wherein without prior discovery cross-examination cannot be expected successfully to perform its historic function, and effective evidence in rebuttal, though perhaps in existence, cannot be produced forthwith upon the close of the claimant's defense, I feel that here there is sufficient showing of necessity, within the rule of *Hickman v. Taylor* if applicable here, to allow the discovery to proceed.

"Based upon the issues involved, the need of the Government for the desired information, the lack of other sources, and the foregoing authority, this Court hereby overrules objections to Interrogatories Nos. 11 and 12.

"Counsel will submit order."

An order was entered in accordance with the opinion and the interrogatories were answered by the claimants. Thereafter, the Government filed a motion for summary judgment. On 10-20-59, the claimants filed a motion to withdraw their claim and answer. On 10-29-59, an order was entered by the court withdrawing claimant's claim and answer and directing that the article be condemned and destroyed. On 11-16-59, the article was destroyed.

6214. Vi-San Food Supplement. (F.D.C. No. 42462. S. Nos. 36-446 M, 11-762 P, 11-769 P.)

INFORMATION FILED: 4-27-59, S. Dist. Calif., against Vi-San Nutritional Laboratories, a corporation, Burbank, Calif.

SHIPPED: Between 9-27-57 and 3-25-58, from Burbank, Calif., to Detroit, Mich.